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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,293

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Hasso Meinert

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EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

07/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,293

Applicant(s)

MEINERT ET AL

Examiner

ERNST V. ARNOLD

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-31, 33, 34 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-31, 33, 34 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date 4/29/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-16, 32, 35, 36 and 38 have been cancelled. Claims 17-31, 33, 34 and 37 are under examination. Applicant has amended the claims and has supplied a new IDS on 4/29/08 which has resulted in a new grounds of rejection. Accordingly, this action is FINAL.

Information Disclosure Statement

The German language reference B3 EP 0037905A1 has only been considered to the extent that it corresponds to US 4,390,518.

Withdrawn rejections:

Applicant's amendments and arguments filed 4/07/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Tal et al. (Journal of Biological Chemistry 1980, 260(18) 9976-9980).

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Tal et al. disclose a physiologically compatible aqueous solution consisting essentially of brilliant blue R, 1% w/v ethanol and trichloroacetic acid thus anticipating instant claim 37 (see Materials and methods at the bottom of page Page 9978). Tal et al. disclose the ability of Brilliant Blue R to bind proteins and act as a stain (Abstract; introduction and Figures 1b and 2 on page 9979, for example).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-31, 33, 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melles WO 99/58160 in view of Hammann IV et al. (US 5,122,432).

Applicant claims:

17. (currently amended) A method for staining cells in ~~a the~~ human or animal body, the method comprising applying to the cells in the body a physiologically compatible aqueous solution of a dye , said dye consisting essentially of brilliant blue R ~~which does not represent a vital dye and is biocompatible .~~

37. (currently amended) A physiologically compatible aqueous dye solution for coloring cells in the human or animal body, the dye solution consisting essentially of brilliant blue R ~~comprising at least one dye which does not represent a vital dye and is biocompatible.~~

Determination of the scope and content of the prior art

(MPEP 2141.01)

Melles teaches in claim 1:

1. A method for performing a capsulorhexis, wherein a lens capsule of an eye is stained using at least one dye, which dye is capable of staining tissue without diffusing through said tissue.

Melles teaches in claims 5-7:

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5. A staining composition suitable for use in a method according to any of the preceding claims, which composition comprises at least one dye which is capable of staining tissue without diffusing through said tissue.

6. A staining composition according to claim 5, wherein the dye is chosen from the group of trypan blue, trypan red and brilliant crsylv blue.

7. A staining composition according to claim 5 or 6, wherein the composition has the form of a physiologically compatible solution.

8. A staining composition according to claim 7, wherein the at least one dye is present in a concentration
5 between 0.001 and 2 wt.%, based on the weight of the solution.

9. A staining composition according to claims 5-8, which further comprises between 0.8 and 1.0 wt.%, based on the weight of the solution, of a salt.

Melles teach a capsulorhexis procedure with excising the anterior capsule of the eye (which can be viewed as an organ of the body) which reads on the limitation of instant claims 17-20). Melles also disclose adding a salt which can be aqueous NaCl (page 10, example I and Claim 9). Melles teaches an in-vivo cataract extraction, thus reading on ophthalmologic surgery, with a visco-elastic substance (Example II page 10). In the absence of evidence to the contrary, the lens capsule/retina/epiretinal/diseased membranes of the eye is colored and delimited in the method of Melles. Melles teaches a physiologically compatible solution (page 7, lines 24-34). Melles teaches adding a buffer, such as phosphate buffered NaCl to control the pH between 6.5 and 7.5 that one of ordinary skill in the art can select (page 8, lines 4-10).

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Hammann IV et al. teach in column 7, lines 34-60:

Water soluble dyes with absorption peaks in the 650 nm region, which are useful in association with cyan microcapsules include Acid Alizarian Violet N, Acid Blue 25, Acid Blue 29, Acid Blue 40, Acid Blue 41, Acid Blue 45, Acid Blue 80, Acid Blue 92, Acid Blue 120, Acid Blue 129, Acid Blue 161, Acid Violet 5, Acid Violet 7, Acid Violet 17, Alcian Blue GX, Alizarian Violet 3R, Aniline Blue, Aniline Blue W. S., Basic Blue 41, Basic Blue 47, Basic Blue 66, Basovit Blue 665 E, Brilliant Blue G, Brilliant Blue R, Brilliant Cresyl Blue, Bromophenol Blue, Celestine Blue, Chicago Sky Blue 6B, Coomassie Brilliant Blue G-250, Coomassie Brilliant Blue R-250, Direct Blue 71, Direct Violet 51, Disperse Blue 1, Disperse Blue 3, Disperse Blue 14, Eriochrome Blue Black B, Ethyl Violet, Evans Blue, Indigo Carmine, Luxol Fast Blue ARN, Meldola's Blue, Methyl Violet 3B, Mordant Blue 13, Naphthol Blue Black, Oxazine 4 Perchlorate, Oxazine 170 Perchlorate, Prussian Blue, Reactive Blue 2, Reactive Blue 4, Remazol Brilliant Blue R, Solar Blue RCLL Supra Powder, Trypan Blue, for reducing the film speed of cyan microcapsules include Basic Blue 3, Brilliant Cresyl Blue ALD, DOTC Iodide, HDITC Perchlorate, HITC Iodide, HITC Perchlorate, Luxol Fast Blue MBSN, Methylene blue, New Methylene Blue N, Nile Blue A, Oxazine 1 Perchlorate, Patent Blue VF, and Reactive Blue 15. GL.

Thus, Hammann IV et al. establish the equivalence of Brilliant Blue R with Trypan Blue and brilliant cresyl blue to one of ordinary skill in the art.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Melles is that Melles do not expressly teach using Brilliant Blue R in a concentration of between about 0.3 and 2.5 g/l or where the concentration is about 1.2 g/l in the method. This deficiency in Melles is cured by the teachings of Hammann IV et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use Brilliant Blue R, as suggested by Hammann IV et al., in the method of Melles and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Hamman IV et al. teach the equivalence of Brilliant Blue R with Trypan Blue and brilliant cresyl blue that are used in the method of Melles. It is merely substituting one equivalent dye for another. Once the solution of brilliant blue R is made than claim 37 is obvious. With regards to the concentration of the dye, it is deemed merely routine optimization of the amounts taught by Melles to arrive at the instantly claimed amounts. Clearly the amount of a specific ingredient in a composition is a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of dye needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of dye amounts would have been obvious at the time of applicant's invention.

From recent case law: "the results of ordinary innovation are not the subject of exclusive rights under the patent laws." (KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. 550 U. S. ____ (2007) page 24).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Applicant's amendments and Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 4/29/08 prompted the new ground(s) of rejection presented in this Office action. Accordingly,

THIS ACTION IS MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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